REGULATORY GUIDE

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

REGULATORY GUIDE 3.2

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES OF RADIOACTIVE MATERIAL

1. INTRODUCTION

PURPOSE AND SCOPE

The purpose of this guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for a specific license for laboratories and industries using millicurie quantities of radioactive material.

This guide is intended to provide you, the applicant and licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to laboratory and industrial use of small quantities of radioactive material. The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program.

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) 180 NAC “Control of Radiation”. The information you provide in your application should be clear, specific, and accurate.

APPLICABLE REGULATIONS

180 NAC applicable to specific license for laboratory and industrial use of small quantities of radioactive material are in 180 NAC 10, "Notices, Instructions and Reports to Workers; Inspections"; 180 NAC 4, "Standards for Protection Against Radiation"; 180 NAC 3-011, "General Requirements for the Issuance of Specific Licenses"; other pertinent regulations are 180 NAC 3-016 through 3-022, 180 NAC 3-025 through 3-028, 180 NAC 13, "Transportation of Radioactive Material"; 180 NAC 15, "Training and Experience Requirements for Use of Radiation Sources"; 180 NAC 17, "Enforcement of Radiation Control Act and Rights to Hearing Procedures for Licensees and Registrants; Penalties" and 180 NAC 18, "Fees for Certificates of

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Title 180 Nebraska regulations, “Control of Radiation”, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Nebraska Department of Health and Human Services Regulation and Licensure Department, Public Health Assurance Division, Radioactive Materials Program, to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Nebraska Department of Health and Human Services, Regulation and Licensure, Public Health Assurance Division, Radioactive Materials Program, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 69509.

Requests for single copies of issued guides (which may be reproduced) should be made in writing to the Nebraska Department of Health and Human Services, Regulation and Licensure Department, Public Health Assurance Division Radioactive Materials Program, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509.

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Registration, Radioactive Material(s) Licenses, Environmental Surveillance and Implementation, Emergency Planning, Emergency Response and Implementation and other Regulatory Services."

2. LICENSE FEES

An application fee is required for all specific licenses and must be submitted with any NEW application. The applicant should refer to 180 NAC 1-018 to determine the amount that should accompany the application. Review of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to the Nebraska Department of Health and Human Services Regulation and Licensure.

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed annually according to the expiration month of their current license.

3. FILING AN APPLICATION

An application for radioactive material license should be completed on Form NRH-5 provided by the Agency. Complete Items 1 through 5, and 15 on the form. For Items 6 through 14, submit additional information on supplementary pages if needed. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. You should complete all items in the application in sufficient detail for the Public Health Assurance Division to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and to minimize danger to life and property.

The forms should be completed in duplicate. Retain one copy for yourself, because the license will require that you possess and use radioactive material in accordance with the statements and representations in your application and in any supplements to it.

Mail the original application to the Nebraska Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509.

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4. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of Form NRH-5.

Item 1(a). Applicant's Name and Mailing Address

Individuals should be designated as the applicant only if they are acting in a private capacity and the use of the radioactive material is not connected with their employment with a corporation or other legal entity. Otherwise, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be the mailing address to which correspondence should be sent. This may or may not be the same as the address at which the material will be used, as specified in Item 1(b).

Item 1(b). Locations of Use

Specify each location of storage or use by the street address, city, and State or other descriptive address (such as 3 miles west on Highway 81, Any town, State). A Post Office Box address is not acceptable. Also, specify whether a location is one at which operations will be conducted or whether the location is only the storage of sources and devices. If operations will be conducted at temporary job sites, specify. If a device will be used in a permanent facility or facilities, give the specific address of each if different from 1(a).

Item 2. Person to be Contacted About Application

Name the individual who knows your program and can answer questions about the application. Also, please note the telephone number at which the individual may be contacted. If the contact changes, notify the Agency. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 3. Self-explanatory

Item 4. Individual User(s)

Specify the names of the persons who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 5. Individuals Responsible for Radiation Safety Program

All licensees must have a Radiation Safety Officer (RSO) or Radiation Protection Officer (RPO) designated by and responsible to the corporation's management for the coordination of the radiation protection program. A statement should be included with the application outlining the named individual's duties and responsibilities. The radiation protection officer is expected to coordinate the safe use of radioactive materials and to ensure compliance with Title 180 and conditions of the license.

Typical duties of the radiation protection officer would be:

To assure that radioactive materials possessed under the license conform to the materials listed on the license.

To assure that radioactive materials are used only by individuals authorized by the license.

To assure that radioactive materials are properly secured against unauthorized removal at all times when they are not in use.

To serve as a point of contact and give assistance in case of emergency to assure that proper authorities are notified promptly in case of accident or damage to radioactive devices.

To assure that the terms and conditions of the license, such as periodic leak tests, are met and that the required records are maintained.

Item 6. Radioactive Material Data

Describe the radioactive material by isotope, chemical and/or physical form, and activity, in millicuries or microcuries. A separate possession limit for each nuclide should be specified. Possession limits requested should cover the total anticipated inventory, including stored materials and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

If the use of sealed or plated sources is contemplated, the isotope, manufacturer, and model number of each sealed source or plated source should be specified. If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device should be specified.

The use to be made of the radioactive materials should be clearly described. Sufficient detail should be given to allow a determination of the potential for exposure to radiation and radioactive materials both of those working with the materials and of the public.

Items 7 and 8. Training and Experience

These items must be completed for each individual(s) named in Item 4 and 5, use supplemental sheets if necessary. Submit a resume of the training and experience of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibilities for radiological safety. Training should cover (a) principles and practices of radiation protection, (b) radioactive measurements,

standardization, and monitoring techniques and instruments, © mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The description of the use of radioactive materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, and the type of use. The qualifications, training, and experience of each person should be commensurate with the material and its use as proposed in the application.

Training and Experience Requirements for Laboratory and Industrial Use of Radioactive Material Personnel are as follows:

For Millicurie Quantities
Radiation Safety Officer and/or Authorized User:

A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

Forty (40) hours of formal instruction in:

Radiation physics and instrumentation;

Radiation protection;

Mathematics pertaining to the use and measurement of radioactivity; and

Biological effects of radiation; and

Demonstrate an understanding of operating and emergency procedures and 180 NAC 1 or their equivalent.

For Microcurie Quantities
Radiation Safety Officer and/or Authorized User:

Forty (40) hours of formal instruction in:

Radiation physics and instrumentation;

Radiation protection;

Mathematics pertaining to the use and measurement of radioactivity; and

Biological effects of radiation; and

Demonstrate an understanding of operating and emergency procedures and 180 NAC 1 or their equivalent.

Items 9 and 10. Radiation Detection Instruments and Calibration of Instruments

Specify for each radiation detection instrument the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detected (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness in mg/cm^2 and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring.

Describe the instrument calibration procedure. State the frequency, and describe the methods and procedures for the calibration of survey and monitoring instruments, as well as any other instruments and systems used in the radiation protection program, such as measuring instruments used to assay sealed-source leak-test samples (see Item 13), contamination samples (e.g., air samples, surface "wipe" samples), and bioassay samples (see Item 11).

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily operation checks of survey instruments be supplemented every twelve (12) months with a two-point (1/3 and 2/3 of the full scale reading) calibration on each scale of each instrument. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

If the applicant proposes to calibrate his survey instruments, a detailed description of planned calibration procedures should be submitted. The description of calibration procedures should include, as a minimum:

A. The manufacturer and model number of each radiation source to be used.

B. The nuclide and quantity of radioactive material contained in each source.

C. The accuracy of the source(s). The traceability of the source to a primary standard should be provided.

D. The step-by-step procedures, including associated radiation safety procedures, and

E. The name and pertinent experience of each person who will perform the calibrations.

If the applicant intends to contract out the calibration of instruments, the name, address, and license number of the firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Agency. If information concerning calibration procedures has not been filed, it should be obtained and submitted.

Quantitative measuring instruments used to monitor the adequacy of containment and contamination control such as those used for measuring leak test, air effluent, bioassay, work area, and equipment contamination samples should usually be calibrated prior to each use. The procedures and frequency for calibration of such instruments should be submitted and should include:

A. The name of the manufacturer and model number of each of the standards to be used.

B. The nuclide and quantity of radioactive material contained in each of the standard sources.

C. A statement of the accuracy of each of the standard sources. The source accuracy should be, as a minimum, ± 5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Bureau of Standards.

D. Step-by-step calibration procedure and, if appropriate, associated radiation safety procedures, and

E. The name and pertinent experience of each person who will perform the instrument calibrations.

Item 11. Personnel Monitoring Devices

180 NAC 4-022 states the conditions requiring individual monitoring of external and internal occupational dose.

Personnel dosimeters that require processing to determine the radiation dose to a worker to compare to the 180 NAC 4-005, 4-011 and 4-012 dose limits must be processed and evaluated at a dosimetry processor per 180 NAC 4-021.03, that is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP).

If personnel monitoring equipment will be used, the name of the organization furnishing film badge, optically stimulated luminescent dosimeter (OSLD) or thermoluminescent dosimeter (TLD) service and the frequency for changing badges, dosimeters, etc., should be specified. If pocket chambers or pocket dosimeters will be used, the useful range of the device, in milliroentgens, the frequency of reading, and the procedures for maintaining and calibrating the devices should be specified.

If personnel monitoring will not be used, the applicant should submit calculations or documentation from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 180 NAC 4-022.

Item 12. Facilities and Equipment

The facilities and equipment for each site of use should be described in detail. The proposed facilities and equipment for each operation to be conducted should be adequate to protect health and minimize danger to life and property in describing available facilities and equipment, the following should be included, as appropriate:

A. Physical plant, laboratory, or working area facilities. Fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, and all processing, work, and protective clothing change areas should be described. A drawing or sketch should be submitted showing the location of all such equipment and the relationship of areas where radioactive materials will be handled to unrestricted areas where radioactive materials will not be handled. In those programs where radioactive material may become airborne or may be included in airborne effluents, the drawing or sketch should also include a schematic description of the ventilation system annotated to show airflow rates, differential pressures, filtration and other effluent treatment equipment, and air and effluent monitoring instruments. Drawings or sketches should be drawn to a specified scale, or dimensions should be included on each drawing or sketch. Each drawing or sketch should be labeled to specify the location of the facilities and equipment depicted with respect to the address(es) given in Item 1.(b) of Form NRH-5.

B. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Special provisions for shielding and containment to minimize personnel exposure should be described. Storage containers and facilities should provide both shielding and security for materials.

C. The number, type, and length of remote handling devices.

D. If respiratory protective equipment will be used to limit the inhalation of airborne radioactive material, the provisions of 180 NAC 4-005 should be followed and appropriate information should be submitted.

Item 13. Radiation Protection Program

A. Survey Program

Agency regulations require that surveys be made to determine if radiation hazards in a facility in which radioactive materials are used or stored (See 180 NAC 4-021). A survey should include the evaluation of external exposure to personnel, concentrations of airborne radioactive material in the facility, and radioactive effluents from the facility. Although a theoretical calculation is often used to demonstrate compliance with regulations regarding airborne or external radiation, it cannot always be used in lieu of a physical survey.

Except for those cases where sources of radiation and radioactive material are well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement instruments to determine the nature and extent of radiation and radioactive material or, as a minimum, confirm the results of a theoretical determination.

A radiation protection program should include the following surveys for radioactive contamination and radiation:

(1) In laboratory or plant areas (e.g., checking for contamination on bench tops, handling and storage equipment, clothing, hands).

(2) While work is being done with radiation or radioactive materials (e.g., breathing zone air surveys; general air surveys; personnel exposure measurements, including eyes and extremities; checking shutters and containment).

(3) In areas associated with disposal or release of radioactive materials (e.g., checking disposal containers and disposal sites; liquid, gas, and solid effluents, filters and filter-duct systems.)

The frequency of surveys will depend on the nature of the radioactive materials and their use. However, surveys should be performed prior to use of radioactive materials in order to establish a baseline. The surveys should be repeated when radioactive materials are present, when the quantity or type of material present changes, or when changes occur in their containment systems or methods of use. Repetitive surveys may also be necessary to control the location of radioactive materials in the handling system and in the case of the use of sealed sources outside a shielded container.

For operations involving materials in gas, liquid, or finely divided forms, the survey program should be designed to monitor the adequacy of containment and control of the materials involved. The program should include air sampling, monitoring of effluents, and surveys to evaluate contamination of personnel, facilities, and equipment. Physical effluent measurements are essential to determine compliance with Appendix 4-B of 180 NAC 4.

The description of an air sampling program should include the area where samples will be taken, the frequency of sampling, and the location of the sampler with respect to workers' breathing zones. Assays performed to evaluate air samples and the methods used to evaluate air samples and the methods used to relate results to actual personnel exposures should also be described.

The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid radioactive material releases. Theoretical evaluations should be supplemented by stack monitoring, water sampling, and other environmental monitoring appropriate for the planned and potential releases.

For operations involving only sealed sources, a survey program should include evaluation and/or measurement of radiation levels for storage and use configurations. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be performed following any changes in operation, shielding, or use.

The types, methods, and frequency of surveys should be described in the application. Guidance may be obtained from the National Council on Radiation Protection Report No. 57. "Instrumentation and Monitoring Methods for Radiation Protection," and the International Atomic Energy Agency's Technical Report Series No. 120, "Monitoring of Radioactive Contamination on Surfaces."

B. Bioassay Procedures

The applicant should show that the need for bioassays has been thoroughly considered and should establish the adequacy of the proposed bioassay program in relation to the proposed program of use of radioactive material. Bioassays are normally required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 depending on the type of work, equipment, and procedures followed. Nebraska's Regulatory Guide 3.3, "Guide for Bioassay Requirements for I-125 and I-131," and Nebraska's Regulatory Guide 3.7, "Criteria For Establishing A Tritium Bioassay Program" may be consulted. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be considered and discussed in relation to each such material, procedures, etc.

The criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures should be specified and described in detail. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well-thought-out and well-executed handling procedures.

C. Records Management Program

Provision for keeping and reviewing records of surveys; materials inventories; personnel exposures; receipt, use, and disposal of materials, etc., should be described. Persons responsible for keeping and reviewing records should be identified.

D. Emergency Procedures

Submit a copy of your emergency procedures. These instructions should be addressed to all persons in all laboratory or facility areas where radioactive materials will be used and should cover actions to be taken in case of such accidents involving radioactive materials as spills, fires, release or loss of material, or accidental contamination of personnel. Specifically, these instructions should (a) specify immediate actions to be taken in order to prevent or limit the contamination of personnel and areas, e.g., the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas, containment of any spills of radioactive material, (b) give the telephone numbers of individuals to be notified in case of emergency, and (c) instruct personnel in proper entry, decontamination, and recovery operations for contaminated facilities. (Note: Only properly trained individuals should attempt decontamination and recovery operations).

E. Sealed-Source Leak-Test Procedures

Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha emitter must be leak tested at 6-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at 3-month intervals. If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit," the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information should be submitted.

(1) Qualification of personnel who will perform the leak test,

(2) Procedures and materials to be used in taking test samples,

(3) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples,

(4) Instrument calibration procedures, including calibration source characteristics, make, and model number, and

(5) The method, including a sample calibration, to be used to convert instrument reading to units of activity, e.g., microcuries.

Item 14. Waste Disposal

The procedures for disposing of radioactive material waste should be described. Under Title 180, a licensee may dispose of waste in the following ways:

A. Transfer to a person properly licensed to receive such waste in conformance with 180 NAC 4-049.01. The name of the firm (which should be contacted in advance to determine any limitations that the firm may have on acceptance of waste) should be given.

B. Release into a sanitary sewer in conformance with 180 NAC 4-041. Depending on water usage, releases of up to 1 curie per year are permitted.

C. Release into air or water in concentrations in conformance with 180 NAC 4-014. Possible exposure to persons offsite limits the amount that may be released.

D. Treatment or disposal by incineration in conformance with 180 NAC 4-042. This must be specifically approved by the Agency.

E. Other methods specifically approved by the Agency pursuant to 180 NAC 4-040.

Item 15. Certification

If you are an individual applicant acting in a private capacity, you are required to sign the form. Otherwise, your application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

5. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the Title 180.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; Title 180 do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application Form NRH-5 or in letter form should be submitted to the address specified in Section 3 of this guide. Your application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license amendment should specify the new individual's name, training, and experience. The qualifications of the new responsible individual should be equivalent to those specified in Item 5 of Section 4 of this guide.

6. RENEWAL OF A LICENSE

Licenses are issued for a period of up to five years. You must send an application for renewal to the address specified in Section 3 of this guide. You are required to submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information.

If you file your application for license renewal at least 30 days before the expiration date of your license, your present license will automatically remain in effect until the Agency takes final action on your renewal application. However, if you file an application less than 30 days before the expiration date and the Agency cannot process it before that date, you would be without a valid license when your license expires.
If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess and send a notification of disposition of the materials with a request for license termination (See 180 NAC 18) before the expiration date.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating Agency regulations that do not allow you to possess licensable material without a valid license.